

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Jeannette Whitcomb	Confirmation No.:	4994
Application No.:	10/758,683	Art Unit:	1648
Filed:	January 14, 2004	Examiner:	Parkin, Jeffrey S.
For:	METHOD OF ASSESSING THE EFFECTIVENESS OF A NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITOR (NNRTI) ON A HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)- INFECTED PATIENTS		
		Attorney Docket No:	11068-078-999

**REQUEST FOR RECONSIDERATION OF
PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705(b)**

Mail Stop ISSUE FEE
 Commissioner for Patents
 P.O. Box 1450
 Alexandria, VA 22313-1450

Sir:

Applicants received a Notice of Allowance and Fee(s) Due ("Notice") mailed February 24, 2009, from the U.S. Patent and Trademark Office ("PTO") in connection with Application No. 10/758,683 (hereinafter "the '683 application"). Accompanying the Notice was a Determination of Patent Term Adjustment under 35 U.S.C. 154 (b), which indicated that the patent term adjustment to date is 327 days for the '683 application.

This petition is being filed prior to payment of the issue fee and thus is timely under 37 C.F.R. § 1.705(b).

Applicants hereby respectfully request reconsideration of the patent term adjustment indicated in the Notice. Specifically, Applicants believe that the patent term adjustment

should be increased by 968 days to a total of **1295 days**. The basis for this petition and the required fees are set forth below.

REMARKS

A request for reconsideration of patent term adjustment under 37 C.F.R. § 1.705(b) must be accompanied by:

- (1) the fee set forth in 37 C.F.R. § 1.18(e); and
- (2) a statement of the facts involved, specifying:
 - (i) the correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment;
 - (ii) the relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) to which the patent is entitled;
 - (iii) whether the patent is subject to a terminal disclaimer and any expiration date specified in the terminal disclaimer; and
 - (iv)(A) any circumstances during the prosecution of the application resulting in the patent that constitute a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704; or
(B) that there were no circumstances constituting a failure to engage in reasonable efforts to conclude processing or examination of such application as set forth in 37 C.F.R. § 1.704.

See 37 C.F.R. § 1.705(b).

In support of this request, Applicants submit the following:

1. Fee Required Under 37 C.F.R. § 1.705(b)(1)

Pursuant to 37 C.F.R. §§ 1.705(b)(1) and § 1.18(e), the fee required for filing this application is believed to be **\$200.00**.

Please charge the required fee to Jones Day Deposit Account No. 50-3013
(referencing 949677-999076).

2. Statement Required Under 37 C.F.R. § 1.705(b)(2)

Pursuant to 37 C.F.R. § 1.702(b)(2), Applicants submit the following statement of facts in support of this application:

- (i) The correct patent term adjustment and the basis or bases under 37 C.F.R. § 1.702 for the adjustment are as follows:

1. Correct patent term adjustment:

The correct patent term adjustment is 1295 days, which is attributable to (a) the failure of the PTO to mail a notification under 35 U.S.C. § 132 not later than fourteen months after the date on which the '683 application was filed under 35 U.S.C. 111(a) (delay under 37 C.F.R. § 1.702(a)(1)); and (b) the failure of the PTO to issue a patent within three years of the actual filing date of the '683 application (delay under 37 C.F.R. § 1.702(b)).

2. Bases under 37 C.F.R. § 1.702 for the adjustment:

(a) Delay under 37 C.F.R. § 1.702(a)(1)

The delay by the PTO under 37 C.F.R. § 1.702(a)(1) is 569 days.

As acknowledged by the PTO in its calculation of the patent term adjustment, the PTO failed to mail a notification under 35 U.S.C. § 132 within fourteen months from the date of filing of the '683 application. *See* PTO's Patent Application Information Retrieval page for U.S. Application No. 10/758,683, at Patent Term Adjustment History ("PTO PAIR Adjustment," Exhibit A). The '683 application was filed under 35 U.S.C. § 111(a) on January 14, 2004. The first notification under 35 U.S.C. § 132 (a Restriction Requirement) was mailed by the PTO on October 4, 2006. Accordingly, the PTO did not mail a notification under 35 U.S.C. § 132 or a notice of allowance under 35 U.S.C. § 151 within fourteen months after the date on

which the application was filed (or by March 14, 2005), and thus, the term of the patent should have been adjusted because the notification under 35 U.S.C. § 132 was delayed by 569 days, which is the period of time from March 14, 2005, to October 4, 2006. 37 C.F.R. § 1.702(a)(1).

(b) Delay under 37 C.F.R. § 1.702(b)

The delay by the PTO under 37 C.F.R. § 1.702(b) is 968 days.

The '683 application was filed under 35 U.S.C. § 111(a) on January 14, 2004. A Notice of Allowance ("Notice") under 37 U.S.C. § 1.311 was mailed on February 24, 2009. The Notice indicates that a patent will issue from the '683 application on the Tuesday before six and a half months from the day the Notice was mailed, which is estimated to be September 8, 2009. Accordingly, the PTO failed to issue a patent within three years of the date on which the application was filed (or by January 14, 2007), and thus, the term of the patent should have been adjusted because issuance was delayed by at least 968 days, which is the period of time from January 14, 2007, to September 8, 2009. 37 C.F.R. § 1.702(b). Applicants further note that Applicants may be entitled to the additional days between September 8, 2009, and the actual date of issuance of the patent, if the PTO fails to issue the patent on September 8, 2009. *Id.* This delay in issuance of the patent was not included by the PTO in its calculation of patent term adjustment (*see* "PTO PAIR Adjustment," Exhibit A).

According to 35 U.S.C. § 154(b)(2)(A): "To the extent that periods of delay attributable to grounds specified in paragraph (1) *overlap*, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." *See* 35 U.S.C. § 154(b)(2)(A).

According to 37 C.F.R. § 1.703(f): "The term of a patent entitled to adjustment under § 1.702 and this section shall be adjusted for the sum of the periods calculated under paragraphs (a) through (e) of this section, to the extent that such periods are not *overlapping*" (emphasis added). *See* 37 C.F.R. § 1.703(f).

Applicants respectfully submit that under controlling case law the delay under 37 C.F.R. § 1.702(a)(1) does not overlap the delay under 37 C.F.R. § 1.702(b) for the ‘683 application.

In *Wyeth et al. v. Dudas* (hereinafter *Wyeth*) the District Court for the District of Columbia clarified the meaning of 35 U.S.C. § 154(b)(2)(A). See *Wyeth et al. v. Dudas*, Civil Action No. 07-1492 (JR), United States District Court for the District of Columbia, 2008 U.S. Dist. LEXIS 76063 (D.D.C., September 30, 2008), attached hereto as Exhibit B. In *Wyeth*, the court held that: “The only way that periods of time can ‘overlap’ is if they occur on the same day. If an ‘A delay’ occurs on one calendar day and a ‘B delay’ occurs on another, they do not overlap.” *Wyeth*, 2008 U.S. Dist. LEXIS 76063, 9-10.

Turning to the ‘683 application, the period of delay under 37 C.F.R. § 1.702(a)(1) occurred from March 14, 2005, fourteen months from the date on which the application was filed, to October 4, 2006, the date on which a Restriction Requirement was mailed by the PTO. The period of delay under 37 C.F.R. § 1.702(b) occurred from January 14, 2007, three years from the date on which the application was filed, to September 8, 2009. Thus, the delay under 37 C.F.R. § 1.702(a)(1) (March 14, 2005 to October 4, 2006) occurred on different calendar days than the delay under 37 C.F.R. § 1.702(b) (January 14, 2007, to September 8, 2009). Consequently, under 35 U.S.C. § 154(b)(2)(A), the delay under 37 C.F.R. § 1.702(a)(1) does not overlap the delay under 37 C.F.R. § 1.702(b) for the ‘683 application, and therefore the total delay under 37 C.F.R. § 1.702 for the adjustment should be a summation of the delays under 37 C.F.R. § 1.702(a)(1) and 37 C.F.R. § 1.702(b), or at least 1537 days (the sum of 569 and 968 days).

- (ii) The relevant dates as specified in 37 C.F.R. §§ 1.703(a) through (e) for which an adjustment is sought and the adjustment as specified in 37 C.F.R. § 1.703(f) are as follows:

1. Adjustment under 37 C.F.R. §§ 1.703(a) through (e):

An adjustment is sought under 37 C.F.R. § 1.703(a)(1), which provides, in relevant part, that the period of adjustment is “[t]he number of

days, if any, in the period beginning on the day after the date that is fourteen months after the date on which the application was filed under 35 U.S.C. 111(a) and ending on the date of mailing of either an action under 35 U.S.C. 132, or a notice of allowance under 35 U.S.C. 151, whichever occurs first.”

The patent term adjustment calculated by the PTO correctly included the time period under 37 C.F.R. § 1.702(a)(1) for the period beginning March 14, 2005 (fourteen months after the date on which the ‘683 application was filed), and ending October 4, 2006, the date the Restriction Requirement was mailed from the PTO. Applicants confirm that this period consists of 569 days.

An adjustment is sought under 37 C.F.R. § 1.703(b), which provides, in relevant part, that “the period of adjustment under 37 C.F.R. § 1.702(b) is the number of days, if any, in the period beginning on the day after the date that is three years after the date on which the application was filed under 35 U.S.C. 111(a)...and ending on the date a patent was issued.”

Applicants submit that this period consists of 968 days. Applicants further submit that the delay under 37 C.F.R. § 1.702(a)(1) does not overlap the delay under 37 C.F.R. § 1.702(b), as explained above.

Accordingly, Applicants’ believe that the delays attributable to the PTO under 37 C.F.R. § 1.702 total 1537 days (the sum of 569 and 968 days), not 569 days as calculated by the PTO.

2. Adjustment under 37 C.F.R. § 1.703(f):

As discussed in section (i) above, Applicants believe that the total delay by the PTO under 37 C.F.R. § 1.702(a)(1) and (b) amounts to 1537 days. As discussed in section (iv) below, Applicants believe that the total delay attributable to Applicants under 37 C.F.R. § 1.704 amounts to 242 days. Applicants believe that the total period of adjustment due under 37 C.F.R. § 1.703(f) is 1295 days, which is the sum of the periods by the PTO calculated under 37 C.F.R. §§ 1.702(a) through (e) (*i.e.*, 1537 days), to the extent that

such periods are not overlapping, less the sum of the periods calculated under Section 1.704 (*i.e.*, 302 days).

- (iii) The '683 application is not subject to a terminal disclaimer.
- (iv) The circumstances during the prosecution of the '683 application that might constitute a failure to engage in reasonable efforts to conclude processing or examination of the '683 application as set forth in 37 C.F.R. § 1.704 are believed to consist of the following:
 - 1. a delay of 92 days by Applicants under 37 C.F.R. § 1.704(b) due to Applicants' filing of an Amendment and Response on September 12, 2007, in response to the non-final Office Action mailed on March 12, 2007;
 - 2. a delay of 60 days by Applicants under 37 C.F.R. § 1.704(b) due to Applicants' filing of an Amendment and Response on April 28, 2008, in response to the non-final Office Action mailed on November 28, 2007; and
 - 3. a delay of 90 days by Applicants under 37 C.F.R. § 1.704(b) due to Applicants' filing of an Amendment and Response on January 23, 2009, in response to the final Office Action mailed on July 25, 2008.

37 C.F.R. § 1.704(b) provides, in relevant part: "[A]n applicant shall be deemed to have failed to engage in reasonable efforts to conclude processing or examination of an application for the cumulative total of any periods of time in excess of three months that are taken to reply to any notice or action by the Office making any rejection, objection, argument, or other request, measuring such three-month period from the date the notice or action was mailed or given to the applicant, in which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date that is three months after the date of mailing or transmission of the Office communication notifying the applicant of the rejection, objection, argument, or other request and ending on the date the reply was filed."

The patent term adjustment calculated by the PTO correctly included the above time periods under 37 C.F.R. § 1.704(b). *See* PTO PAIR Adjustment, Exhibit A. Applicants confirm that the sum of the above time period consists of 242 days.

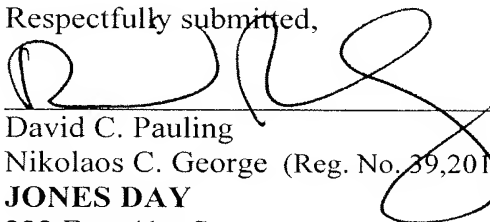
CONCLUSION

In summary, the total adjustment under 37 C.F.R. § 1.702(a)(1) and (b) is 1537 days, the total delays attributable to Applicants under 37 C.F.R. § 1.704 are 242 days, and thus the total period of adjustment due under 37 C.F.R. § 1.703(f) is believed to be 1295 days. Accordingly, Applicants respectfully request an adjustment of patent term under 37 C.F.R. § 1.703(f) totaling **1295 days**.

In accordance with 37 C.F.R. § 1.705(b), this request for reconsideration of patent term adjustment is being filed no later than the payment of the issue fee and not earlier than the date of mailing of the notice of allowance for Application No. 10/758,683, and thus is timely filed.

Date: May 22, 2009

Respectfully submitted,



David C. Pauling

For: Nikolaos C. George (Reg. No. 39,201)

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EXHIBIT A: PTO PAIR Adjustment

10/758,683	METHOD OF ASSESSING THE EFFECTIVENESS OF A NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITOR (NNRTI) ON A HUMAN IMMUNODEFICIENCY VIRUS TYPE 1 (HIV-1)-INFECTED PATIENTS.	05-22-2009::17:28:08
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Patent Term Adjustments

Patent Term Adjustment (PTA) for Application Number: 10/758,683

Filing or 371(c) Date:	01-14-2004	USPTO Delay (PTO) Delay (days):	569
Issue Date of Patent:	-	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL) Delay (days):	242
Post-Issue Petitions (days):	+0	Total PTA (days):	327
USPTO Adjustment(days):	+0	Explanation Of Calculations	

Patent Term Adjustment History

Date	Contents Description	PTO(Days)	APPL(Days)
02-24-2009	Mail Notice of Allowance		
02-19-2009	Document Verification		
02-19-2009	Notice of Allowance Data Verification Completed		
02-18-2009	Examiner's Amendment Communication		
01-23-2009	Notice of Appeal Filed		
02-12-2009	Date Forwarded to Examiner		
01-23-2009	Amendment after Final Rejection		90
01-23-2009	Request for Extension of Time - Granted		⬆
07-25-2008	Mail Final Rejection (PTOL - 326)		⬆
07-21-2008	Final Rejection		
05-13-2008	Date Forwarded to Examiner		
04-28-2008	Response after Non-Final Action		60
04-28-2008	Request for Extension of Time - Granted		⬆
11-28-2007	Mail Non-Final Rejection		⬆
11-26-2007	Non-Final Rejection		
09-12-2007	Substitute Specification Filed		
09-14-2007	Date Forwarded to Examiner		
09-12-2007	Response after Non-Final Action		92
09-12-2007	Request for Extension of Time - Granted		⬆
03-12-2007	Mail Non-Final Rejection		⬆
03-05-2007	Non-Final Rejection		
02-15-2007	Case Docketed to Examiner in GAU		
02-15-2007	Case Docketed to Examiner in GAU		
02-13-2007	Case Docketed to Examiner in GAU		
12-21-2006	Date Forwarded to Examiner		
12-04-2006	Response to Election / Restriction Filed		
12-04-2006	Request for Extension of Time - Granted		
10-04-2006	Mail Restriction Requirement	569	
10-02-2006	Requirement for Restriction / Election	⬆	
07-07-2004	Information Disclosure Statement considered	⬆	

12-03-2004	Information Disclosure Statement considered	⬆
12-03-2004	Information Disclosure Statement (IDS) Filed	⬆
12-03-2004	Information Disclosure Statement (IDS) Filed	⬆
11-08-2004	Preliminary Amendment	⬆
11-08-2004	Workflow incoming amendment IFW	⬆
10-28-2004	IFW TSS Processing by Tech Center Complete	⬆
10-28-2004	Mail Non-Compliant Preliminary Amendment	⬆
10-28-2004	Non-Compliant Preliminary Amendment	⬆
09-27-2004	Preliminary Amendment	⬆
07-07-2004	Reference capture on IDS	⬆
07-07-2004	Information Disclosure Statement (IDS) Filed	⬆
07-07-2004	Information Disclosure Statement (IDS) Filed	⬆
01-14-2004	Preliminary Amendment	⬆
10-28-2004	Case Docketed to Examiner in GAU	⬆
10-14-2004	Application Return from OIPE	⬆
10-14-2004	Application Return TO OIPE	⬆
10-14-2004	Application Dispatched from OIPE	⬆
10-14-2004	Application Is Now Complete	⬆
09-27-2004	Payment of additional filing fee/Preexam	⬆
01-14-2004	Claim Preliminary Amendment	⬆
07-26-2004	Notice Mailed--Application Incomplete--Filing Date Assigned	⬆
03-17-2004	Cleared by L&R (LARS)	⬆
03-04-2004	Referred to Level 2 (LARS) by OIPE CSR	⬆
01-28-2004	IFW Scan & PACR Auto Security Review	⬆
01-14-2004	Initial Exam Team nn	⬆

Close Window

EXHIBIT B:

***Wyeth et al. v. Dudas*, Civil Action No. 07-1492 (JR), United States District Court for the District of Columbia, 2008 U.S. Dist. LEXIS 76063 (D.D.C., September 30, 2008)**

1 of 1 DOCUMENT

WYETH, et al., Plaintiffs, v. JON W. DUDAS, Under Secretary of Commerce for
Intellectual Property and Director of U.S. Patent and Trademark Office, Defendant.

Civil Action No. 07-1492 (JR)

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

2008 U.S. Dist. LEXIS 76063

September 30, 2008, Filed

COUNSEL: [*1] WYETH, Plaintiff: David O. Bickart,
LEAD ATTORNEY, Patricia A. Carson, PRO HAC
VICE, KAYE SCHOLER LLP, Washington, DC.

For ELAN PHARMA INTERNATIONAL LIMITED,
Plaintiff: David O. Bickart, LEAD ATTORNEY, KAYE
SCHOLER LLP, Washington, DC.

For JON W. DUDAS, Honorable, Under Secretary of
Commerce, Defendant: Fred Elmore Haynes, LEAD
ATTORNEY, U.S. ATTORNEY'S OFFICE, Washing-
ton, DC.

JUDGES: JAMES ROBERTSON, United States District
Judge.

OPINION BY: JAMES ROBERTSON

OPINION

MEMORANDUM OPINION

Plaintiffs here take issue with the interpretation that the United States Patent and Trademark Office (PTO) has imposed upon 35 U.S.C. § 154, the statute that prescribes patent terms. Section 154(a)(2) establishes a term of 20 years from the day on which a successful patent application is first filed. Because the clock begins to run on this filing date, and not on the day the patent is actually granted, some of the effective term of a patent is consumed by the time it takes to prosecute the application. To mitigate the damage that bureaucracy can do to inventors, the statute grants extensions of patent terms for certain specified kinds of PTO delay, 35 U.S.C. § 154(b)(1)(A), and, regardless of the reason, whenever the patent prosecution [*2] takes more than three years. 35 U.S.C. § 154(b)(1)(B). Recognizing that the protection provided by these separate guarantees might overlap,

Congress has forbidden double-counting: "To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed." 35 U.S.C. § 154(b)(2)(A). Plaintiffs claim that the PTO has misconstrued or misapplied this provision, and that the PTO is denying them a portion of the term Congress has provided for the protection of their intellectual property rights.

Statutory Scheme

Until 1994, patent terms were 17 years from the date of issuance. See 35 U.S.C. § 154 (1992) ("Every patent shall contain . . . a grant . . . for the term of seventeen years . . . of the right to exclude others from making, using, or selling the invention throughout the United States. . . ."). In 1994, in order to comply with treaty obligations under the General Agreement on Tariffs and Trade (GATT), the statute was amended to provide a 20-year term from the date on which the application is first filed. See Pub. L. No. 103-465, § 532, 108 Stat. 4809, 4984 (1994). [*3] In 1999, concerned that extended prosecution delays could deny inventors substantial portions of their effective patent terms under the new regime, Congress enacted the American Inventors Protection Act, a portion of which -- referred to as the Patent Term Guarantee Act of 1999 -- provided for the adjustments that are at issue in this case. Pub. L. No. 106-113, §§ 4401-4402, 113 Stat. 1501, 1501A-557 (1999).

As currently codified, 35 U.S.C. § 154(b) provides three guarantees of patent term, two of which are at issue here. The first is found in subsection (b)(1)(A), the "[g]uarantee of prompt Patent and Trademark Office response." It provides a one-day extension of patent term for every day that issuance of a patent is delayed by a failure of the PTO to comply with various enumerated

statutory deadlines: fourteen months for a first office action; four months to respond to a reply; four months to issue a patent after the fee is paid; and the like. *See* 35 U.S.C. § 154(b)(1)(A)(i)-(iv). Periods of delay that fit under this provision are called "A delays" or "A periods." The second provision is the "[g]uarantee of no more than 3-year application pendency." Under this provision, a one-day [*4] term extension is granted for every day greater than three years after the filing date that it takes for the patent to issue, regardless of whether the delay is the fault of the PTO. ¹ *See* 35 U.S.C. § 154(b)(1)(B). The period that begins after the three-year window has closed is referred to as the "B delay" or the "B period". ("C delays," delays resulting from interferences, secrecy orders, and appeals, are similarly treated but were not involved in the patent applications underlying this suit.)

1 Certain reasons for exceeding the three-year pendency period are excluded, *see* 35 U.S.C. § 154(b)(1)(B)(i)-(iii), as are periods attributable to the applicant's own delay. *See* 35 U.S.C. § 154(b)(2)(C).

The extensions granted for A, B, and C delays are subject to the following limitation:

(A) In general.--To the extent that periods of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.

35 U.S.C. § 154(b)(2)(A). This provision is manifestly intended to prevent double-counting of periods of delay, but understanding that intent does not answer [*5] the question of what is double-counting and what is not. Proper interpretation of this proscription against windfall extensions requires an assessment of what it means for "periods of delay" to "overlap."

The PTO, pursuant to its power under 35 U.S.C. § 154(b)(3)(A) to "prescribe regulations establishing procedures for the application for and determination of patent term adjustments," has issued final rules and an "explanation" of the rules, setting forth its authoritative construction of the double-counting provision. The rules that the PTO has promulgated essentially parrot the statutory text, *see* 37 C.F.R. § 1.703(f), and so the real interpretive act is found in something the PTO calls its Explanation of 37 CFR 1.703(f) and of the United States Patent and Trademark Office Interpretation of 35 U.S.C. § 154(b)(2)(A), which was published on June 21, 2004, at 69 Fed. Reg. 34238. Here, the PTO "explained" that:

the Office has consistently taken the position that if an application is entitled to an adjustment under the three-year pendency provision of 35 U.S.C. § 154(b)(1)(B), the entire period during which the application was pending before the Office (except for periods excluded under [*6] 35 U.S.C. § 154(b)(1)(B)(i)-(iii)), and not just the period beginning three years after the actual filing date of the application, is the relevant period under 35 U.S.C. § 154(b)(1)(B) in determining whether periods of delay "overlap" under 35 U.S.C. 154(b)(2)(A).

69 Fed. Reg. 34238 (2004) (emphasis added). In short, the PTO's view is that any administrative delay under § 154(b)(1)(A) overlaps any 3-year maximum pendency delay under § 154(b)(1)(B): the applicant gets credit for "A delay" or for "B delay," whichever is larger, but never A + B.

In the plaintiffs' submission, this interpretation does not square with the language of the statute. They argue that the "A period" and "B period" overlap only if they occur on the same calendar day or days. Consider this example, proffered by plaintiff: A patent application is filed on 1/1/02. The patent issues on 1/1/08, six years later. In that six-year period are two "A periods," each one year long: (1) the 14-month deadline for first office action is 3/1/03, but the first office action does not occur until 3/1/04, one year late; (2) the 4-month deadline for patent issuance after payment of the issuance fee is 1/1/07, but the patent does not [*7] issue until 1/1/08, another year of delay attributable to the PTO. According to plaintiff, the "B period" begins running on 1/1/05, three years after the patent application was filed, and ends three years later, with the issuance of the patent on 1/1/08. In this example, then, the first "A period" does not overlap the "B period," because it occurs in 2003-04, not in 2005-07. The second "A period," which covers 365 of the same days covered by the "B period," does overlap. Thus, in plaintiff's submission, this patent holder is entitled to four years of adjustment (one year of "A period" delay + three years of "B period" delay). But in the PTO's view, since "the entire period during which the application was pending before the office" is considered to be "B period" for purposes of identifying "overlap," the patent holder gets only three years of adjustment.

Chevron Deference

We must first decide whether the PTO's interpretation is entitled to deference under *Chevron v. NRDC*, 467 U.S. 837, 104 S. Ct. 2778, 81 L. Ed. 2d 694 (1984). No,

the plaintiffs argue, because, under the Supreme Court's holdings in *Gonzales v. Oregon*, 546 U.S. 243, 126 S. Ct. 904, 163 L. Ed. 2d 748 (2006), and *United States v. Mead Corp.*, 533 U.S. 218, 121 S. Ct. 2164, 150 L. Ed. 2d 292 (2001), Congress has not "delegated [*8] authority to the agency generally to make rules carrying the force of law," and in any case the interpretation at issue here was not promulgated pursuant to any such authority. See *Gonzales*, 546 U.S. at 255-56, citing *Mead*, 533 U.S. at 226-27. Since at least 1996, the Federal Circuit has held that the PTO is not afforded *Chevron* deference because it does not have the authority to issue substantive rules, only procedural regulations regarding the conduct of proceedings before the agency. See *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996).

Here, as in *Merck*, the authority of the PTO is limited to prescribing "regulations establishing procedures for the application for and determination of patent term adjustments under this subsection." 35 U.S.C. § 154(b)(3)(A) (emphasis added). Indeed, a comparison of this rulemaking authority with the authority conferred for a different purpose in the immediately preceding section of the statute makes it clear that the PTO's authority to interpret the overlap provision is quite limited. In 35 U.S.C. § 154(b)(2)(C)(iii) the PTO is given the power to "prescribe regulations establishing the circumstances that constitute a failure of an applicant [*9] to engage in reasonable efforts to conclude processing or examination of an application" (emphasis added) -- that is, the power to elaborate on the meaning of a particular statutory term. No such power is granted under § 154(b)(3)(A). *Chevron* deference does not apply to the interpretation at issue here.

Statutory Construction

Chevron would not save the PTO's interpretation, however, because it cannot be reconciled with the plain text of the statute. If the statutory text is not ambiguous enough to permit the construction that the agency urges, that construction fails at *Chevron's* "step one," without regard to whether it is a reasonable attempt to reach a result that Congress might have intended. See, e.g., *MCI v. AT&T*, 512 U.S. 218, 229, 114 S. Ct. 2223, 129 L. Ed. 2d 182 (1994) ("[A]n agency's interpretation of a statute is not entitled to deference when it goes beyond the meaning that the statute can bear.").

The operative question under 35 U.S.C. § 154(b)(2)(A) is whether "periods of delay attributable to grounds specified in paragraph (1) overlap." The only way that periods of time can "overlap" is if they occur on the same day. If an "A delay" occurs on one calendar day and a "B delay" occurs on another, they do not [*10] overlap, and § 154(b)(2)(A) does not limit the extension to one day. Recognizing this, the PTO defends its inter-

pretation as essentially running the "period of delay" under subsection (B) from the filing date of the patent application, such that a period of "B delay" *always overlaps* with any periods of "A delay" for the purposes of applying § 154(b)(2)(A).

The problem with the PTO's construction is that it considers the application *delayed* under § 154(b)(1)(B) during the period *before it has been delayed*. That construction cannot be squared with the language of § 154(b)(1)(B), which applies "if the issue of an original patent is *delayed* due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years." (Emphasis added.) "B delay" begins when the PTO has failed to issue a patent within three years, not before.

The PTO's interpretation appears to be driven by Congress's admonition that any term extension "not exceed the actual number of days the issuance of the patent was delayed," and by the PTO's view that "A delays" during the first three years of an applications' pendency inevitably lead to "B delays" in later years. Thus, as the PTO sees it, if [*11] plaintiffs' construction is adopted, one cause of delay will be counted twice: once because the PTO has failed to meet an administrative deadline, and again because that failure has pushed back the entire processing of the application into the "B period." Indeed, in the example set forth above, plaintiffs' calendar-day construction does result in a total effective patent term of 18 years under the (B) guarantee, so that -- again from the PTO's viewpoint -- the applicant is not "compensated" for the PTO's administrative delay, he is benefited by it.

But if subsection (B) had been intended to guarantee a 17-year patent term and *no more*, it could easily have been written that way. It is true that the legislative context -- as distinct from the legislative history -- suggests that Congress may have intended to use subsection (B) to guarantee the 17-year term provided before GATT. But it chose to write a "[g]uarantee of no more than 3-year application pendency," 35 U.S.C. § 154(b)(1)(B), not merely a guarantee of 17 effective years of patent term, and do so using language separating that guarantee from a different promise of prompt administration in subsection (A). The PTO's efforts to [*12] prevent windfall extensions may be reasonable -- they may even be consistent with Congress's intent -- but its interpretation must square with Congress's words. If the outcome commanded by that text is an unintended result, the problem is for Congress to remedy, not the agency.

JAMES ROBERTSON

United States District Judge